JUL 16 2004

510(k) Summary

1.	Name:	Quinton Cardiology, Inc.
2.	Address:	3303 Monte Villa Parkway Bothell, WA 98021-8969
3.	Phone number:	(425) 402-2255
4.	Fax number:	(425) 402-2017
5.	Contact person:	Karen Browne
6.	Summary prepared:	June 14, 2004
7.	Proprietary name:	Q-Tel RMS (Rehabilitation Management System)
8.	Common name:	Telemetry system
9.	Classification name:	§ 870.1025 Arrhythmia detector and alarm § 870.1425 Programmable diagnostic computer § 870.2050 Biopotential amplifier and signal conditioner § 870.2300 Cardiac monitor § 870.2340 Electrocardiograph § 870.2810 Paper chart recorder § 870.2900 Patient transducer and electrode cable § 870.2910 Radiofrequency physiological signal transmitter and receiver

10. The Q-Tel RMS is substantially equivalent to the Q-Tel RMS (K003576).

11. Description: The Q-Tel RMS telemetry system measures the electrical activity of a patient's heart during an exercise class and transmits it via radio frequency to a central monitoring station. The core features of the Q-Tel RMS system include telemetry monitoring, ECG displays, full disclosure of vital signs, printing and reporting, and rehabilitation program management, such as scheduling classes and seminars and patient enrollment.

    The monitoring station displays the patient's real-time ECG waveforms and uses programmable alarms to indicate the presence of pre-selected medical or technical conditions, such as arrhythmia or loss of signal. When alerted by the alarm, the clinician determines whether the event causing the alarm is clinically significant or benign. The Q-Tel RMS system enables the clinician to view, edit, record ECG strips, and use a printer to print reports.

    Optional workstation(s) may be connected to the Q-Tel RMS via a network for the purpose of entering and viewing patient demographic and session data, which is stored on

the Q-Tel RMS system. A workstation may also be used for tracking patient progress in cardiac rehab and displaying non-real-time waveforms and alarms. Workstation(s) may be supplied as a turnkey device or as software only to be installed on specified hardware platform supplied by the customer. The software only workstation provides the same functions as the turnkey workstation except viewing of session data in "read-only" mode.

An optional wireless data entry device, such as a PDA, may act as a station for entry of patient session data which is saved on the Q-Tel RMS system. The wireless entry device has access only to patient session data.

12. Intended use:
    - The device is intended to acquire and transmit electrocardiograph (ECG) data by means of a radio-frequency transmitter worn by individual patients in a hospital or clinical setting to a central monitor where it is received, displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change.
    - The device is to be used on ambulatory adult populations where monitoring is prescribed while undergoing exercise rehabilitation.
    - Multiple central receivers may be used and connected to a local area network.
    - Specified wireless data entry devices may be connected to the system via a wireless access point and be used as a station for entry of patient session data.
    - Optional workstation(s) may be connected to the system via a network for entering and viewing patient demographic and rehab session data. The workstation may also be used for tracking patient progress in cardiac rehab and displaying non-real-time waveforms and alarms.
    - ECG analysis may include 12-lead ECG interpretation.
    - Patient demographics, exercise prescription, scheduling information, and collected data can be ported to an outcomes management program.

13. Technological characteristic comparison: The Q-Tel RMS (K003576) and the proposed device have nearly identical indications for use. The proposed device allows the clinician alternate methods of data entry, and track patient progress in a non-real-time display of waveforms and alarms. This is merely a management tool and has no impact on the safety and efficacy of the device. Both devices are to be to be used on ambulatory adult populations where monitoring is prescribed while undergoing exercise rehabilitation. Both devices are based on personal computer (PC) platforms. The predicate device utilized a Pentium III processor while the proposed device utilizes a Pentium IV processor or greater, a proven performance improvement. Both devices use Windows 2000 operating system coupled with SQL 2000 (MDSE). Both devices utilize the frequency bands of ISM 904.7 to 925.16 MHz, WMTS 608.48 to631.52 and ISM 2400.96 to 2482.56. Both devices use the identical Mortara Instrument, Inc. Ambulatory X-12 Telemetry Module (K974149) incorporated as a component to accomplish the aforementioned frequencies. The predicate and proposed devices utilize identical Mortara analysis algorithms previously incorporated in the Datex-Ohmeda CS/3 Telemetry System (K000882). Material differences between the two devices are consistent with design. Both devices perform identically, aside from the capability of the proposed device to allow remote methods of data entry and viewing of non-real-time display of waveforms and alarms. This represents a clinical process improvement and

has no impact on the safety and/or efficacy of the device. Sterilization is not required for either device. Both devices utilize a biocompatible medical grade Santoprene that come into contact with the patient (patient leads). Mechanical safety, aside from stability, is not applicable for either device. Stability testing of the predicate and proposed devices was performed in accordance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, respectively. Chemical safety is not applicable for either device. Both devices are used in identical anatomical sites. Both devices include optional 4 and 5 lead combinations. Human factors for both devices are similar. Generated data is identical. Both devices are passive and floating. The existing and proposed devices 2 AA batteries. The batteries represent safety extra low voltage (SELV) levels and are used for radio-frequency (RF) transmission only. The proposed device complies with IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility. The proposed and predicate device comply to IEC 60601-1-2 Electromagnetic compatibility and CISPR 11 Industrial, scientific, and medical (ISM and WMTS) radio-frequency equipment – Electromagnetic disturbance characteristics. Both devices are used in a clinical or hospital environment. Electrical safety testing of the predicate and proposed devices was performed in accordance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. Additionally, the predicate and proposed device complies with EN 60601-2-25, Medical electrical equipment. Part 2: Particular requirements for the safety of electrocardiographs. IEC 60601-2-25: 1993, 1995. Thermal safety of the predicate and proposed devices is assured by compliance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. Ionizing energy is not emitted by neither device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Quinton Cardiology, Inc.
c/o Ms. Karen Browne
Director, Quality Assurance and Regulatory Affairs
3303 Monte Villa Parkway
Bothell, WA 98021-8969

Re: K041607
Trade Name: Q-Tel RMS
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II (two)
Product Code: MHX
Dated: June 14, 2004
Received: June 15, 2004

Dear Ms. Browne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D. for
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041607

510(k) Number (if known):_____

Device Name: Q-Tel RMS

Indications For Use:

- The device is intended to acquire and transmit electrocardiograph (ECG) data by means of a radio-frequency transmitter worn by individual patients in a hospital or clinical setting to a central monitor where it is received, displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change.
- The device is to be used on ambulatory adult populations where monitoring is prescribed while undergoing exercise rehabilitation.
- Multiple central receivers may be used and connected to a local area network.
- Specified wireless data entry devices may be connected to the system via a wireless access point and be used as a station for entry of patient session data.
- Optional workstation(s) may be connected to the system via a network for entering and viewing patient demographic and rehab session data. The workstation may also be used for tracking patient progress in cardiac rehab and displaying non-real-time waveforms and alarms.
- ECG analysis may include 12-lead ECG interpretation.
- Patient demographics, exercise prescription, scheduling information, and collected data can be ported to an outcomes management program.

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041607